



Attorney's Docket No. 030662-066

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Keiko NERIISHI et al.

Application Serial No.: 09/749,410

Filed: December 28, 2000

For: DNA DETECTION DEVICE

Group Art Unit: 1655

Examiner: A. Chakrabarti

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AMENDMENT AND REPLY

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In response to the Office Action dated November 6, 2001, please amend the above-captioned patent application as follows.

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IN THE CLAIMS:

Please replace claims 1 as follows:

1. (Amended) A process for detecting a complementary DNA fragment which comprises the steps of:

bringing single-stranded sample DNA fragments having a radioactive label in a liquid phase into contact with a DNA micro-array having a support and at least two defined areas in each of which a group of probe compounds selected from the group consisting of DNA molecules, DNA fragments, synthesized oligonucleotides, synthesized polynucleotides, and PNA (peptide nucleic acid), are fixed under such condition that a group of the probe compounds fixed in one area differs from a group of the probe

compounds fixed in another area, so that DNA fragments complementary to a group of the probe compounds are fixed by hybridization to the area in which the last-mentioned group is fixed;

removing unfixed sample DNA fragments from the DNA micro-array;

Q / keeping the DNA micro-array in contact with a radiation image storage panel containing a stimuable phosphor via a spacer sheet having openings in areas corresponding to the areas on which groups of the probe compounds are fixed, so that the stimuable phosphor sheet can absorb and store radiation energy of the radioactive label coming from the fixed DNA fragments through the openings;

irradiating the radiation image storage panel with a stimulating light, so that the image storage panel releases a stimulated emission from the area in which the radiation energy is stored;

detecting the stimulated emission photoelectrically to obtain a series of electric signals; and

processing the electric signals to locate the area in which the complementary DNA fragments are fixed.

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**REMARKS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested. By the present amendment, claim 1 has been amended to recite "probe compounds" rather than "nucleotide derivatives and analogues thereof." Support for this amendment to claim 1 may be found, at the very least, on page 7, lines 27 to 33. Support for a DNA micro-array having a support may be found in Figure 1, no. 14, and at page 5, lines 22-23. No new matter has been added by the present amendment.

**Rejection of Claims 1-3 Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-3 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. According to the Examiner, it is unclear what is meant by "nucleotide derivatives or analogues." In order to clarify the claims, and in no acquiescing to the correctness of this rejection, applicants have amended the claims to remove this phrase. In light of this amendment, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

**Rejection of Claims 1-3 Under 35 U.S.C. § 102(e)**

Claims 1-3 have been rejected under 35 U.S.C. § 102(e) for purportedly being anticipated by Some et al (U.S. Patent No. 6,256,405). For at least all of the reasons set forth below, applicants respectfully request withdrawal of this rejection.

Some et al discloses a method for detecting complementary DNA fragments which comprises the steps of:

- (a) bringing single-stranded probe DNA fragments having a radioactive label in a liquid phase into contact with a sample DNA fixed onto a transfer support;
- (b) removing unfixed probe DNA fragments;
- (c) keeping the hybridized DNA in contact with a radiation image storage panel;
- (d) irradiating the radiation image storage panel with a stimulating light;
- (e) detecting the stimulated emission photoelectrically;
- (f) processing the electric signals to locate the area in which the complementary DNA fragments are fixed.

Thus, in the method of Some et al, the DNA fragments to be tested are fixed to the transfer support, whereas the known probes are hybridized to the fixed DNA fragments to be tested. See column 7, lines 21-39. Note that the sample DNA fragments are first eletrophoresed on a gel medium and then transferred onto a transfer support according to the known Southern blotting method.

In contrast, in the claimed invention, the single-stranded probe is fixed on a micro-array, and the radioactively labeled DNA fragment to be tested is brought into contact with the micro-array.

Furthermore, in the claimed invention, a spacer sheet, which has openings, is placed between the DNA micro-array and the radiation image storage panel in step (c). The DNA micro-array has probe compounds in predetermined areas, and thus it is easy to prepare a spacer sheet which has openings in the positions corresponding to the probe-fixed

area. These openings allow for the emission of radioactive energy by the hybridized radioactively labeled DNA fragment without disturbance and noise.

Some et al does not disclose or suggest the use of a spacer having openings which is placed between the DNA micro-array and the radiation image storage panel in step (c). In the Official Action, the Examiner refers to figures 1 and 8, and column 7, lines 43-50, for support for step (c). However, no spacer is seen in figures 1 and 8. Furthermore, the description in column 7, lines 43-50, reads as follows:

The thus obtained transfer support and the stimuable phosphor sheet 1 are placed in layers for a certain period of time to expose the stimuable phosphor sheet 1 and at least a part of radiation emitted from the radioactively labeled substance on the transfer support is absorbed in the stimuable phosphor sheet 1, whereby the locational information regarding the radioactively labeled substance in the specimen is stored in the stimuable phosphor sheet 1.

It is therefore clear that a spacer having openings is not described in Some et al.

The Examiner also states at the bottom of page 4 of the Official Action that the spacer sheet is made of a non-radiation-transmitting material. However, the non-radiation-transmitting material is actually employed for the production of the light guiding sheet, which is indicated in Figures 1 and 8 by the number 8. There is no relationship between a spacer, as is used in the claimed invention, and the light guiding sheet.

To summarize, Some et al does not disclose fixing probe DNA fragments to a micro-array and bringing single-stranded sample DNA fragments in contact therewith. Furthermore, Some et al does not disclose or suggest using a spacer sheet having openings

which is placed between the DNA micro-array and the radiation image storage panel in step (c). Therefore, Some et al does not anticipate the claimed invention.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 102(e).

**Rejection of Claims 1-3 Under 35 U.S.C. § 103(a)**

Claims 1-3 have been rejected under 35 U.S.C. § 103(a) for purportedly being obvious over Some et al in view of Linsley et al (U.S. Patent No. 6,271,002) and further in view of Ward et al (U.S. Patent No. 4,711,955). For at least all of the reasons set forth below, withdrawal of this rejection under 35 U.S.C. § 103(a) is respectfully requested.

As noted above, Some et al fails to disclose, or even suggest, some of the key features of the claimed invention. For example, Some et al does not disclose fixing probe DNA fragments to a micro-array and bringing single-stranded sample DNA fragments in contact therewith. Furthermore, Some et al does not disclose or suggest using a spacer sheet having openings which is placed between the DNA micro-array and the radiation image storage panel in step (c).

Linsley et al does not solve the deficiencies of Some et al. As can be seen in column 26, lines 47-53, Linsley et al discloses fixing sample DNA fragments to a micro-array and bringing probe DNA fragments in contact therewith. Furthermore, there is no disclosure or suggestion in Linsley et al to use a spacer sheet having openings which is placed between a DNA micro-array and a radiation image storage panel. Therefore,

Linsley et al does not disclose or suggest a few of the key features of the claimed invention, and does not solve the deficiencies of Some et al.

Ward et al does not solve the deficiencies of Some et al or Some et al taken together with Linsley et al. Ward et al does not disclose fixing probe DNA fragments to a micro-array and bringing single-stranded sample DNA fragments in contact therewith. Furthermore, Ward et al does not disclose or suggest using a spacer sheet having openings which is placed between a DNA micro-array and a radiation image storage panel.

Therefore, even if the disclosures of Some et al, Linsley et al and Ward et al were taken together, one would not arrive at the claimed invention. This is because none of these references disclose or suggest fixing probe DNA fragments to a micro-array and bringing single-stranded sample DNA fragments in contact therewith. Furthermore, none of these references disclose or suggest using a spacer sheet having openings which is placed between a DNA micro-array and a radiation image storage panel.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

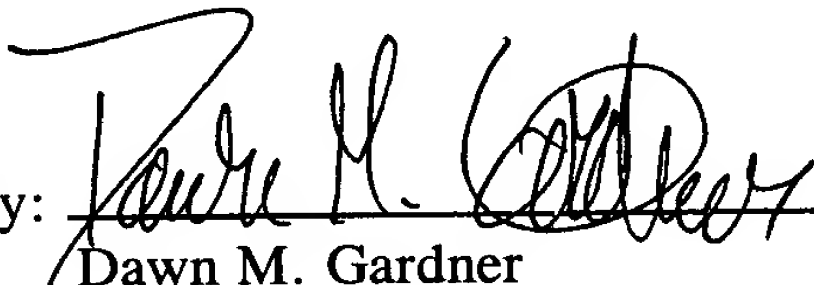
### CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned agent concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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